



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

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FEB 19 1995

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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

The enclosed application for extension of the patent term of U.S. Patent No. 4,303,651 issued on December 1, 1981, was filed on February 15, 1995, under 35 USC § 156.

Your assistance is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is **NOT** to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156.

Gerald A. Dost
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Burton A. Amernick
Pollock, Vande Sande & Priddy
1990 M Street, N.W.
P.O. Box 19088
Washington, D.C. 20036